Remarks

Claims 21-25 and 34-42 were the subject of the office action dated December 14, 2007. Claims 38, 39, and 42 were withdrawn from consideration; these claims are canceled accordingly without prejudice. Claims 43-51 are added.

Thus, claims 21-25, 34-37, 40-41, and 43-51 are now presented for further consideration.

Claim 24 is amended in light of claim 22. Language removed from claim 36 is now presented in claim 50.

Claims 21, 34, 36, and 51 are the independent claims.

Claim 51 corresponds to claim 34 but specifies at least 95% identity.

The following claims depend directly or indirectly from claim 21: 22-25 and 43-45.

The following claims depend directly or indirectly from claim 34: 35, 40, and 46.

The following claims depend directly or indirectly from claim 36: 37, 41, and 47-50.

Election/Restrictions and Enablement

The applicants respectfully request that the full scope of all of the claims now presented be included within the scope of examination. The applicants also respectfully traverse the remaining enablement rejections.

The applicants acknowledge that SEQ ID NOS:34, 45, and 47 were elected for initial search purposes.

The applicants wish to thank the examiner for also permitting whole proteins for SEQ ID NOS:22, 25, 56, and 57 to be recited in the claims. The applicants appreciate the sequence search burdens placed on the patent office and the examiners, and the applicants acknowledge the efforts that the examiner has made to have additional sequences considered.

On the other hand, the applicants also note that it would be a great burden upon the applicants if the applicants (having an invention relating to novel uses of groups of related proteins) were *de facto* required to pursue piecemeal patent protection one, two, or three sequences at a time.

It is acknowledged by the examiner, on the bottom of page 6 of the office action, that current techniques in the art would allow for mutants having at least 99% identity. Thus, the

enablement rejection of claims 34, 35, and 40 with respect to SEQ ID NOS:34 and 45 was withdrawn.

The applicants submit that the same logic should apply to 95-99% variants of all the sequences now specified in the claims. That is, it should also be acknowledged that current techniques in the art would allow for all such variants.

It is indicated on page 7 of the office action that the portions of claims that recite 99% identity to SEQ ID NOS:22 and 56 are withdrawn from consideration.

Claims 36, 37, and 41 (specifying 95% identity) stand rejected as lacking enablement. The applicants respectfully traverse this rejection.

The enablement rejection of claims 21-25 was withdrawn. However, "consists essentially of" in claim 21 was treated as "comprises" as discussed on page 3 of the office action. In light of this, 95% identity language is now used in claim 21 in place of the "consists essentially of" language.

The applicants certainly do not wish to complain when the examiner indicated a willingness to allow SEQ ID NOS:22, 25, 56, and 57 (without variants) to be specified in the claims (as well as 99% variants of SEQ ID NOS:34, 45, and 47). However, the applicants fail to see why 95-99% variants of all of the specified sequences could not also be fully considered. As discussed in more detail below, the applicants submit that such variants are logical extensions (that are conventional in the art) of what is exemplified in the subject application.

The office action reviews why such variants would include large numbers of possible sequences. However, the applicants respectfully submit this type of pessimistic numerical review is contrary to the patent office's own guidelines and statements about what is conventional in the relevant art.

Example 14 of The Written Description Guidelines (attached), in an almost identical fact pattern, indicates that procedures for making 95% variants (even where variants of this scope are not specifically exemplified (so long as an activity assay is available and the variants have the specified activity) are conventional in the art (as is the case with the current application). The Guidelines state that there is "no substantial variation" in this scope of variants (in light of the structural identity and the common activity).

The applicants note the following quotes from the Guidelines:

> The specification exemplifies a protein isolated from liver that catalyzes the reaction of A B. The isolated protein was sequenced and was determined to have the sequence as set forth in SEQ ID NO: 3. The specification also contemplates but does not exemplify variants of the protein...
>
> The procedures for making variants of SEQ ID NO: 3 are conventional in the art and an assay is described which will identify other proteins having the claimed catalytic activity. Moreover, procedures for making variants of SEQ ID NO: 3 which have 95% identity to SEQ ID NO: 3 and retain its activity are conventional in the art. [*emphasis added*]
>
> The claim has two different generic embodiments, the first being a protein which comprises SEQ ID NO: 3 and the second being variants of SEQ ID NO: 3. There is a single species disclosed, that species being SEQ ID NO: 3. [*emphasis added*]
>
> There is actual reduction to practice of the single disclosed species. [*emphasis added*]
>
> The specification indicates that the genus of proteins that must be variants of SEQ ID NO: 3 does not have substantial variation since all of the variants must possess the specified catalytic activity and must have at least 95% [structural] identity to the reference sequence, SEQ ID NO: 3. [*emphasis added*]

In light of the foregoing, the applicants submit that producing and using 95% variants of all the sequences now specified in the claims is conventional in the art, and such variants are fully enabled by the subject specification. (Beyond the fact pattern of the Guidelines, the subject specification also shows that multiple proteins within the *Xenorhabdus* group can be used with multiple proteins within the *Photorhabdus* group. Thus, the subject specification goes beyond the fact pattern in Example 14 of the Guidelines, where there is "a single disclosed species.")

Likewise, the applicants submit that considering 95-99% variants of all the specified sequences would also be consistent with the state of the art and the Guidelines as discussed above.

In light of all the foregoing, full consideration of all the claims now presented is respectfully requested. In addition, the withdrawal of the remaining enablement rejection is respectfully requested.

Provisional (obviousness-type) double patenting

Any action on this issue in the subject application will be deferred until there is an indication that this application is otherwise allowable. The applicants also note that an election was recently filed in USSN 11/070,573.

The Assistant Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 and 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to allowance.

Respectfully submitted,

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Attachment: Example 14 of The Written Description Guidelines

JMS/mrc

Example 14: Product by Function

Specification: The specification exemplifies a protein isolated from liver that catalyzes the reaction of A $\longrightarrow$ B. The isolated protein was sequenced and was determined to have the sequence as set forth in SEQ ID NO: 3. The specification also contemplates but does not exemplify variants of the protein wherein the variant can have any or all of the following: substitutions, deletions, insertions and additions. The specification indicates that procedures for making proteins with substitutions, deletions, insertions and additions is routine in the art and provides an assay for detecting the catalytic activity of the protein.

Claim:

A protein having SEQ ID NO: 3 and variants thereof that are at least 95% identical to SEQ ID NO: 3 and catalyze the reaction of A $\longrightarrow$ B.

Analysis:

A review of the full content of the specification indicates that a protein having SEQ ID NO: 3 or variants having 95% identity to SEQ ID NO: 3 and having catalytic activity are essential to the operation of the claimed invention. The procedures for making variants of SEQ ID NO: 3 are conventional in the art and an assay is described which will identify other proteins having the claimed catalytic activity. Moreover, procedures for making variants of SEQ ID NO: 3 which have 95% identity to SEQ ID NO: 3 and retain its activity are conventional in the art.

A review of the claim indicates that variants of SEQ ID NO: 3 include but are not limited to those variants of SEQ ID NO: 3 with substitutions, deletions, insertions and additions; but all variants must possess the specified catalytic activity and must have at least 95% identity to the SEQ ID NO: 3. Additionally, the claim is drawn to a protein which **comprises** SEQ ID NO: 3 or a variant thereof that has 95% identity to SEQ ID NO: 3. In other words, the protein claimed may be larger than SEQ ID NO: 3 or its variant with 95% identity to SEQ ID NO: 3. It should be noted that "having" is open language, equivalent to "comprising".

The claim has two different generic embodiments, the first being a protein which comprises SEQ ID NO: 3 and the second being variants of SEQ ID NO: 3. There is a single species disclosed, that species being SEQ ID NO: 3.

A search of the prior art indicates that SEQ ID NO: 3 is novel and unobvious.

There is actual reduction to practice of the single disclosed species. The specification indicates that the genus of proteins that must be variants of SEQ ID NO: 3 does not have substantial variation since all of the variants must possess the specified catalytic activity and must have at least 95% identity to the reference sequence, SEQ ID NO: 3. The single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO: 3 which are capable of the specified catalytic activity. One of skill in the art would conclude that

applicant was in possession of the necessary common attributes possessed by the members of the genus.

Conclusion: The disclosure meets the requirements of 35 USC §112 first paragraph as providing adequate written description for the claimed invention.